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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,173	11/16/2004	Ralf Jager	HUBR-1271-US	6575
24972 7590 06/14/2007 FULBRIGHT & JAWORSKI, LLP 666 FIFTH AVE NEW YORK, NY 10103-3198			EXAMINER SUTTON, DARRYL C	
			ART UNIT 1609	PAPER NUMBER
			MAIL DATE 06/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/510,173	Applicant(s) JAGER ET AL.	
	Examiner Darryl C. Sutton	Art Unit 1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/23/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/24/04 & 3/23/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim 10 is objected to because of the following informalities: The word "compounds" is in the plural. For examination purposes, the examiner is interpreting that "compounds" should be in the singular form to be in agreement with the word "another" which precedes it in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 cites the limitation "short-term intensive muscular exertion and/or muscular exertion of short term duration and/or that is repeated in short intervals" in lines 1-3 of the claim. There is no disclosure that defines or differentiates between terms or that specifically spells out the limits of the claim. Also, the limitation "preferably " in lines 8 of the claim is improper claim language. See MPEP 2173.05.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7, 9, and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone et al. (Int. J. Sport Nutr., 1999).

The claimed invention is directed to a method comprising administering creatine pyruvate to subjects in need thereof to increase stamina during intermittent physical exertion in need thereof (claim 1); or wherein during the short-term intensive muscular exertion and/or muscular exertion of short duration and or that is repeated at short intervals, preferably during sprinting and sporting performances in running disciplines and during exercises on sporting equipment equipped with rollers, wheels or sliding surfaces, and also during raising, pulling and/or lifting movements of the extremities and neck, very particularly preferably during build-up and demonstration measures of the body's muscular apparatus, in ball sports, in impact sports, in rowing sports, in combat sports, in cycling, in sledding sports, in fencing, swimming and skiing sports, in archery, in aerobics and in shooting up movements (claim 2); wherein the exertion lasts for 0.1 seconds to 5 minutes (claim 3); or wherein the muscle exertion occurs at a frequency of 0.1 to 600 per minute (claim 4) or at a frequency of 3 to 120 per minute (claim 12); or wherein the muscular exertion repeats after intervals of 1 second to 5 minutes (claim 5). or after equal intervals of 1 second to 5 minutes (claim 14); or after identical intervals

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(claim 13); or wherein the duration of the repeating muscular exertion is of equal length (claim 6); or wherein the muscular exertion increases from exertion interval to exertion interval (claim 7); or wherein the creatine pyruvate is administered daily (claim 15) over a period of 1 day to 12 weeks (claim 9).

Stone et al. teaches administering creatine pyruvate to test subjects to increase stamina during intermittent physical exertion (page 149 Abstract). The test subjects performed exercises where the exertion lasted between 0.1 seconds and 5 minutes (page 149 paragraphs 1 and 3); and that occurred at a frequency of 0.1 to 600 per minute and between 3 to 120 per minute (page 149 paragraph 3). Stone et al. also teaches that the test subjects performed exercises that repeated after intervals of 1 second to 5 minutes, or wherein the duration of the repeating exercise is of equal length that repeated after equal rest intervals (page 149, paragraphs 1 and 3). Weight lifting exercises were performed where the exertion level was increased from light to moderate sets to major lifting (page 151, Table 1). The creatine pyruvate was administered daily for 5 weeks (Title, page 148, paragraph 2). Stone et al. teaches the use of creatine pyruvate in a test protocol, which reflects improved peak power and the ability to maintain power (stamina) during (intermittent physical exertion) football play page 150, paragraph 1, and page 161 paragraph 3).

Claims 1, 8, 10, 11, 16 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Natural Health Consultants, Creatine Pyruvate, 1998.

The claimed invention is directed to a method comprising administering creatine pyruvate to subjects in need thereof to increasing stamina during intermittent physical exertion (claim 1); wherein creatine pyruvate is administered in a daily dose of 500 mg to 30.0 g (claim 8); or wherein creatine pyruvate is used together with another physiologically active compound (claim 10); wherein said physiologically active compound is an exogenic compound (claim 16) or wherein said another physiologically accepted active compound is selected from the group consisting of caffeine, creatine monohydrate or creatine derivatives different from creatine pyruvate, protein, amino acids and derivatives thereof, fats and phospholipids, carbohydrates, vitamins, minerals and sweeteners, pyruvate derivatives different from creatine pyruvate, keto acids, buffer compounds and mixtures thereof (claim 17); or wherein said creatine pyruvate is administered in powder form, tablet form, capsule form, or dragee form, in liquids, as a food additive and/or food supplement and/or functional food (claim 11).

Natural Health Consultants teaches administering a creatine pyruvate supplement containing vitamin C to test subjects in need thereof to increase stamina during intermittent physical exertion wherein creatine is administered in a daily dose of 500 mg to 30.0 g (page 1, paragraph 1 and page 3, "DOSE"); Natural Health Consultants also teaches creatine pyruvate administered in powder form, tablet form, capsule form, or dragee form, in liquids, as a food additive and/or food supplement and/or functional food (page 1, paragraph 1). Natural Health Consultants (page 1, paragraph 1 and page 2, paragraph 2) teaches the combination of creatine pyruvate

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and vitamin C in a supplement, which energizes muscle for prolonged endurance and optimal work output in activities such as weight lifting and sprinting.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone et al. (Int. J. Sport Nutr., 1999) in view of Kaminski et al. (Pain, 1992).

Stone et al. discloses a creatine pyruvate supplement (Abstract, page 146) that increases stamina during a test protocol of intermittent physical exertion, page 149, paragraphs 1 and 3, page 150, paragraph 1, and page 161, paragraph 3. Stone et al. does not teach a supplement that includes vitamin C.

Kaminski et al. discloses ascorbic acid (vitamin C) used to abate muscle soreness. See Discussion, page 321, lines 19-26, which teach the use of vitamin C to reduce delayed soreness following strenuous physical exertion.

Stone et al. and Kaminski et al. are analogous art because both are nutritional supplements utilized in strenuous physical activity.

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At the time of the invention, it would have been obvious to a person skilled of ordinary skill in the art to modify Stone et al. by preparing a supplement that included vitamin C because it would help to abate soreness after the strenuous intermittent activities, such as those undertaken in the test protocol of Stone et al.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is 571-270-3286. The examiner can normally be reached on M-Th from 8:00 AM to 4:30 AM or Fr from 8:00 AM to 3:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on M-Th from 8:00 AM to 4:00 PM at 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



JEFFREY STUCKER
SUPERVISORY PATENT EXAMINER

